

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CIMA LABS INC., AZUR PHARMA  
LIMITED, and AZUR PHARMA  
INTERNATIONAL III LIMITED  
Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.,  
  
Defendant.

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C.A. No. 10-625-LPS

**MEMORANDUM ORDER**

At Wilmington this 18th day of April, 2011, having considered the motion filed by Plaintiffs CIMA Labs Inc. (“CIMA”), Azur Pharma Limited, and Azur Pharma International III Limited (collectively, “Plaintiffs”) to stay this lawsuit pending resolution of two reexamination proceedings in the U.S. Patent and Trademark Office (the “PTO”) (D.I. 25), and the opposition filed by Defendant Mylan Pharmaceuticals Inc. (“Mylan”) (D.I. 35);

IT IS HEREBY ORDERED that Plaintiffs’ motion to stay is GRANTED for the following reasons:

1. Background. This is a Hatch-Waxman patent infringement action which Plaintiffs initiated against Mylan on July 23, 2010, asserting infringement of U.S. Patent Nos. 6,024,981 (the “981 patent”) and 6,221,392 (the “392 patent”) (together, the “patents-in-suit”). (See D.I. 1) Plaintiffs had received, on June 16, 2010, a Paragraph IV notice letter informing them of Mylan’s ANDA No. 201824, in which Mylan seeks FDA approval to market a generic orally-disintegrating clozapine product. (*Id.* at ¶ 20) Azur Pharma International III Limited holds NDA No. 21-590 and has listed the patents-in-suit in the Orange Book as covering FAZCLO™

clozapine orally-disintegrating tablets in 12.5mg, 25mg, and 100mg dosages. (*Id.* at ¶ 18)

2. Mylan answered Plaintiffs' complaint on December 3, 2010, asserting various affirmative defenses, including failure to state a claim for relief, lack of standing, lack of ownership interest, non-infringement, invalidity under §§ 101, 102, 103, 112, and 116, unclean hands, and patent misuse. (D.I. 17) Mylan also presses counterclaims seeking declarations of non-infringement and invalidity. (*Id.*)

3. Plaintiffs answered Mylan's counterclaims on January 7, 2011. (D.I. 22)

4. Also on January 7, 2011, Plaintiffs filed their motion to stay pending reexamination of the patents-in-suit. (D.I. 25)

5. The same day, the Court requested a proposed scheduling order from the parties. (D.I. 21) On January 31, 2011, the Court held a Rule 16 scheduling conference, but refrained from entering a scheduling order until resolution of the present motion. (D.I. 45)

6. Briefing on the motion to stay was completed on February 2, 2011. (D.I. 37)

7. The parties submitted unsolicited supplemental letters on February 4 (Plaintiffs) and February 9, 2011 (Defendant). (D.I. 42; D.I. 43)

8. The Court held oral argument on the motion to stay on April 6, 2011. (D.I. 52) (hereinafter "Tr.")

9. There are six other related litigations involving the patents-in-suit, three pending before this Court. All six of the related actions have been stayed until resolution of the reexamination proceedings described here. A patent infringement action in the District of Minnesota, which CIMA and Schwarz Pharma, Inc. ("Schwarz") filed against KV Pharmaceutical Co. ("KV"), was stayed in October of 2005 pending the *ex parte* reexamination

of the '981 patent. Two Hatch-Waxman actions are pending in the District of New Jersey: one in which CIMA and Schwarz sued Par Pharmaceutical Companies, Inc., and another in which CIMA and Schwarz sued Actavis Group hf, Actavis, Inc., and Actavis Elizabeth LLC (collectively "Actavis"). Both New Jersey actions were prompted by ANDAs seeking approval to sell generic versions of NIRAVAM™, which the patents-in-suit are listed in the Orange Book as covering. On June 20, 2007, the court presiding over two New Jersey actions (which had been consolidated) granted a stay pending the outcome of the *ex parte* reexamination of the '981 patent and the *inter partes* reexamination of the '392 patent.

10. The three related actions pending before this Court were initiated by Plaintiffs, two against Barr Laboratories, Inc. ("Barr") and one against Novel Laboratories, Inc. ("Novel"). The Barr actions were filed by Plaintiffs upon notice of two ANDAs submitted by Barr seeking approval to market orally-disintegrating clozapine tablets. Both Barr actions are currently stayed pursuant to a joint stipulation by the parties. The Novel action was filed following an ANDA submitted by Novel seeking approval for generic clozapine orally-disintegrating tablets, and was similarly stayed pursuant to a joint stipulation.

11. The '981 patent is the subject of an *ex parte* reexamination, which is the consolidation of two reexaminations requested by KV in August 2005 and September 2006. Following rehearing, the Board of Patent Appeals and Interferences (the "BPAI") recently issued a decision in this proceeding overturning its prior affirmance of an examiner's rejections of certain claims of the '981 patent; the BPAI ultimately rejected claims 1-36, 41-65, and 78-82 of the '981 patent on new grounds. The '392 patent is the subject of an *inter partes* reexamination requested by KV in July 2006. The BPAI recently issued a decision in this proceeding rejecting

claims 2-47 of the '392 patent, entering a new grounds for rejection on fourteen of those claims.

12. Legal Standards. Whether or not to stay litigation pending reexamination by the PTO of the patents-in-suit is a matter left to the Court's discretion. See *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1998). In exercising this discretion, the Court must weigh the competing interests of the parties. See *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936). The factors courts typically consider in deciding how to exercise this discretion are: (1) whether a stay will simplify the issues and trial of the case, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. See *St. Clair Intellectual Property v. Sony Corp.*, 2003 WL 25283239, at \*1 (D. Del. Jan. 30, 2003).

13. Parties' Contentions.

a. Plaintiffs argue a stay is warranted here given that six other actions involving the patents-in-suit have been stayed. They also assert Mylan will suffer no prejudice from a stay, as is evident from Barr and Novel's willingness to stipulate to a stay in their cases. Plaintiffs contend that enduring the automatic thirty-month stay of FDA approval – an almost certain occurrence if this litigation is stayed pending reexamination – poses no potential of additional prejudice to Mylan, given the time required for ANDA approval (i.e., even if the thirty-month stay were lifted early by a favorable judgment here, Mylan still could not launch for some time). Moreover, Plaintiffs believe the reexamination will simplify the issues for trial and that the relative stage of the two proceedings favors a stay.

b. Mylan opposes a stay and is willing to limit this litigation only to disputes over infringement – dropping its contentions regarding invalidity and enforceability – if a stay is

denied. Therefore, Mylan argues, the reexaminations can afford no simplification of the trial, since there would be no overlap of issues. Mylan adds that it will suffer prejudice if a stay is granted, asserting its product is clearly non-infringing and a stay would unjustly permit Plaintiffs to keep its product off the market. In making this argument, Mylan surmises that Barr and Novel have, or will, forfeit the first-filer 180-day exclusivity period, and Mylan will be next in line to obtain such exclusivity. Finally, Mylan argues the prejudice it would suffer outweighs the relative status of the two proceedings.

c. In response, Plaintiffs contend the reexaminations may be finalized within a year, while the instant litigation is only in its early stages, and Mylan's ANDA will be approved, if at all, after the expected conclusion of the reexaminations. Plaintiffs also urge that denying a stay would undermine judicial economy since the three related actions pending before the Court have been stayed. Finally, Plaintiffs contend Mylan's willingness to litigate only infringement does not favor a stay because the infringement case is more complicated than Mylan assumes. In particular, Mylan's prosecution history argument is premature, since prosecution is still underway.

14. Discussion. Turning to the relevant factors, the Court first considers whether a stay would simplify the issues for trial.

a. The potential here for simplification of issues through the reexaminations is significant. All the claims involved in this lawsuit currently stand rejected in the reexaminations. If the latest BPAI decisions withstand appeal, this litigation will be terminated.

b. Mylan asserts no benefit of simplification will accrue because of its willingness to forgo invalidity and non-enforceability arguments, leaving only a simple infringement case

having no overlap with the reexaminations. The Court disagrees. Mylan's position is largely premised on a claim construction argument; because Mylan's claim construction contentions are disputed, so, too, are its non-infringement contentions, leaving the purported simplicity of Mylan's narrowed case very much in question.

c. Further complicating the analysis are the three stayed actions pending before the Court. If the Court were to deny a stay here, it seems likely that Barr and Novel would request their stays be lifted. Pursuant to the stipulated order in the Novel action, "any decision by the Court on Plaintiffs' Motion to Stay in the Mylan Action" terminates the stipulation to stay the Novel action. (*CIMA Labs Inc. et al v. Novel Laboratories Inc.*, C.A. No. 08-886-LPS, D.I. 22) Were the Novel and/or Barr actions to resume imminently, they might well be consolidated with the instant action, and, in this way, the instant action would not be so simple as Mylan suggests.

15. Next, considering the relative status of the two proceedings, the reexaminations are mature while the lawsuit is in its infancy.

a. The reexaminations have progressed, having already undergone their first appeal. The record before the PTO is well developed and may prove useful in this case: the examiner and BPAI have considered thirteen pieces of prior art among the two reexaminations and, currently, eleven rejections stand. The Court acknowledges that the recent developments in the reexaminations point to additional, perhaps lengthy, proceedings in the PTO; nevertheless, the reexaminations have now been pending over four and a half years and are rather far along.

b. By contrast, the instant lawsuit is in its infancy. Although the complaint was filed almost nine months ago, the Court refused (in a recent status conference) to enter a scheduling order until resolution of the instant motion. Thus, no discovery has taken place nor have any

milestone dates been set.

16. Finally, a stay would pose no undue prejudice to Mylan sufficient to outweigh the other considerations.

a. Mylan could conceivably be prejudiced from its inability to lift the automatic thirty-month stay by achieving an early non-appealable judgment of non-infringement in this action. This grounds for finding prejudice, however, is premised on four assumptions: the accused product does not infringe the patents-in-suit; Barr and Novel have forfeited the 180-day exclusivity period, which now falls to Mylan; the instant litigation (including any appeal) can be resolved prior to December 2012 (when the thirty-month stay will expire); and Mylan's ANDA will be approved before December 2012. If any of these assumptions fail (which is quite possible, if not likely), Mylan will suffer no appreciable prejudice.

b. There is potential prejudice to Plaintiffs if a stay is denied. Plaintiffs would be forced to proceed here while its suits against some or all of the other five defendants are stayed, thereby requiring Plaintiffs to litigate the same issues multiple times, in addition to the ongoing proceedings before the PTO. It is noteworthy that, unlike many patent cases in which a motion for stay pending reexamination is filed, the party seeking a stay here did not initiate the reexaminations (and, therefore, did not initiate a reexamination to obtain a tactical advantage).

17. When weighing the interests implicated by a stay motion, the Court is mindful of its "responsibility to secure the just and speedy and inexpensive determination of every action." *Kenney v. Cal. Tanker Co.*, 381 F.2d 775, 777 (3d. Cir 1967) (citing Fed. R. Civ. Proc. 1). The circumstances presented by this case – six related cases involving the patents-in-suit have been stayed pending the reexamination proceedings; under most scenarios, Mylan will suffer no

significant prejudice from a stay; and the lawsuit is in its infancy while the reexaminations are mature – tip the interests against proceeding at this time with this litigation.

Delaware counsel are reminded of their obligation to inform out-of-state counsel of this Order. To avoid the imposition of sanctions, counsel should advise the Court immediately of any problems regarding compliance with this Order.

  
UNITED STATES DISTRICT JUDGE